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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,653

01/14/2006

Gyoon Hee Han

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38051

7590

02/26/2009

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/564,653	HAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-6, 17 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6, 17, 21-28 is/are rejected.
- 7) ☒ Claim(s) 17, 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**An examiner's amendment was proposed to the attorney on February 3<sup>rd</sup>, 2009; however no approval for this proposed amendment was given, thus necessitating the following rejections.**

Applicant's Amendment filed September 26, 2008 has been received and entered into present application. No claims were canceled or added. Claims 23-28, which were previously withdrawn for pertaining to the non-elected invention, have been rejoined. Thus claims 4-6, 17, and 21-28 are pending.

Applicants' arguments, filed September 26, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Objections***

Claims 17 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claims 17 and 22 applicant claims the pharmaceutical composition of claim 4, wherein the disease to be treated is a host of cancers (claim 17) or specifically breast cancer (claim 22). Since

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the claims a drawn to a composition, the intended use (to treat cancer) holds no patentable weight and therefore the claims 17 and 22 fail to further limit the parent claim from which they depend on.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of prostate cancer, does not reasonably provide enablement for the other cancer diseases claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The previously withdrawn method claims have been rejoined. Applicant claims a method of treating mammals in need of treatment of a cancer disease, or more specifically applicant claims a whole host of cancer diseases such as bone cancer, prostate cancer, Hodgkin's disease, and neoplasms of the nervous system. Applicant also specifically claims treatment of breast cancer. Applicant has not shown their invention such that one of skill in the art at the time of the invention could use the claimed compounds to treat anything other than prostate cancer.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546

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(BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

1. The quantity of experimentation necessary to develop a treatment that would be effective against all of the cancer diseases claimed would be very large.

2. There is no direction provided beyond the examples directed towards treatment of prostate cancer, which while enabling treatment of prostate cancer does not provide any direction to the other cancer diseases claimed.

3. The examples provided are directed towards synthesis of the compounds, or treatment of prostate cancer.

4. The nature of the invention is treatment of a multitude of different, and very distinct cancers with different pathologies and treatment options.

5. The state of the prior art is such that treatments for one type of cancer such as prostate are not generally known to be effective against a multitude of different types of cancer.

6. The skill of those of those in the art is high.

7. The unpredictability of cancer treatments is very high, as evidenced by Duffy et al. (page 494, background).

8. The breadth of the claims is very large due to the large number of different cancers named in claim 27, and the generic "a cancer disease" in claim 23.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6, 17, 21-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, applicant claims "a pharmaceutical composition comprising: a compound to treat cancer disease represented by the following formula". This is unclear because one of skill in the art cannot determine if applicant means to claim a composition for treating cancer, comprised by the following formula or if applicant means to claim that the cancer disease which the composition treats is represented by the following formula. Furthermore, since this is a composition claim, the intended use holds no patentable weight and thus the addition of such a term as "to treat cancer disease" is unnecessary and in this case confusing.

In claims 4 and 23, applicant claims "...lower alkynyl, lower allyl group having C1 to C5 carbon atoms". It is not clear if it is only the lower allyl that is limited to C1-C5 carbon atoms or if this applies to all the "lower" groups claimed. If it does not apply those terms are indefinite because one of skill in the art would not know what the limitations on "lower" are.

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Claims 5-6, 17, 21-22, and 24-28 depend from claims 4 and 23 respectively and do not define the claims further to rectify the indefiniteness and thus are also rejected for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 23 recites the limitation "the pharmaceutically acceptable salt" and "the isomer thereof". There is insufficient antecedent basis for this limitation in the claim. The use of the term "the" instead of "a" or "an" implies that there was one specific salt or isomer that was previously referred to the claims are limited to instead of any pharmaceutically acceptable salt or isomer but there is a lack of antecedent basis since there was no previous mention of any salt or isomer.

### ***Conclusion***

No claims are allowed. The claims appear to be free of the prior art.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614